UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of Chemical Safety and Pollution Prevention

MEMORANDUM **02/04/2014**

SUBJECT: Application for registration of Agro-K Yeast Hydrolysate Liquid MUP

EPA File Symbol No.: 48222-O
DP Barcode: 413860
Decision No.: 477691
PC Code: 100054
CAS No.
MRIDs: 49097701

FROM: Miachel Rexrode, Ph.D., Senior Biologist /s/ 02/04/2014
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TO: Gina Burnett, Regulatory Action Leader /s/ 02/04/2014
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CONTAINS CONFIDENTIAL BUSINESS INFORMATION

ACTION REQUESTED

Agro-K Corporation has submitted a request for registration of the product Agro-Yeast Hydrolysate Liquid MUP. The applicant has relied on Cite-All to fulfill data requirements, but the available studies in the Agency data base are for formulations that differ in percent active and inerts and cannot be used to fulfill the data requirements for Agro-Yeast Hydrolysate Liquid MUP (MRIDs 47396909, 47396938, 47396911, 47396909).

RECOMMENDATIONS AND CONCLUSIONS

Certified Limits
The applicant should check the calculated limits and make changes to the CSF.

Physical Chemical Properties:
The following data are required: 830.6317 Storage stability; 830.6320 Corrosion characteristics; 830.7000.

Toxicology
The following requirements should be addressed by the applicant: 870.1200 Acute dermal; 870.1300 Acute Inhalation; 870.2400 Primary Eye Irritation; 870.2500 Primary Dermal Irritation; 870.2600 Dermal Sensitization.

Ecological Non-Target Studies
Since this is a non registered source the applicant must submit acute ecological non-target studies or appropriate rationale to support request for waivers. The required studies include the following: 850.2100 Acute Avian Oral; 850.2200 Acute Avian Dietary; 850.1075 Acute Freshwater Fish; 850.1010 Acute Aquatic Invertebrate.

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1) **Product Identity and Composition (OCSPP 830.1550)**
This product is yeast extract hydrolysate from *Saccharomyces cerevisiae.* This active ingredient consists primarily of oxidized amino acids, but also includes nutrients such as vitamins, and minerals. Brewer's (Baker's) yeast extract, from which the active ingredient is derived, is cleared by the U.S. Food and Drug Administration (FDA) as a flavor enhancer for soups, fruits, and other foods. Because yeast extract is especially rich in B vitamins, it is also used as a human nutritional supplement. The single registered end use product, "KeyPlex 350," in use for more than 20 years as a plant fertilizer, was also found to be useful also in preventing crop diseases. Yeast extract hydrolysate from *Saccharomyces cerevisiae* may act by stimulating natural defense mechanisms in plants. The end product also improves growth, yield, and shelf life of crops.

2) Description of Formulation Process (OCSPP 830.1550 and 830:1650)

BEGINNING MATERIALS
A. BASIC FORMULATION

i. Active Ingredients - 3.10%

[redacted]

Product ingredient source information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

[redacted]

ii. Inert Ingredients - 96.90%

[redacted]

Manufacturing Process

[redacted]

Deficiencies: None

3) Discussion of Formation of Impurities (OCSPP 830.1670)
The product is not produced by an integrated formulation system and there is no reason to believe any impurities are found in this product at a level equal to or greater than 0.1%.
Deficiencies: None

4) Preliminary Analysis (OCSPP 830.1700)
This product is a MUP formulation and is not produced by an integrated formulation system and is not subject to this data requirement.
Deficiencie: None.

5) Certified Limits (OCSPP 830.1750)
Table 1.0 lists the nominal concentrations and certified limits for the ingredients in Agro-K Yeast Hydrolysate Liquid MUP as given on the CSF. The following inconsistancies must be addressed: The lower and upper % concentration of [redacted] should be reversed. The values in parenthesis are the standard calculated limits according to 158.350.
Deficiencies: Check the calculated limits.

Inert ingredient information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

TABLE 1.0. Nominal CSF (07/01/2013) concentrations and certified limits for Agro-K Yeast Hydrolysate Liquid MUP

Ingredients (CAS number and PC)	Suppliers Name and Address	Purpose	Concentration (% by weight)		
			Nominal	Lower	Upper
[redacted] Yeast Extract CAS # 68876-77-7	[redacted]	Active Ingredient	3.1	3.07	2.94
[redacted]				[redacted]	

[redacted]

[a]Data from CSF

6) Enforcement Analytical Method (OCSPP 830.1800)

The purpose of this study is to present an analytical method designed for EPA enforcement purposes. The enforcement analytical method parallels the European Association of Yeast Products (EURASYP) method used by various members. Details are present in MRID 49097701.

Deficiencies: None.

7) Physical and Chemical Properties (OCSPP 830.1800)

Deficiencies: The following data are required: 830.6317 Storage stability; 830.6320 Corrosion characteristics; 830.7000.

TABLE 2.0. Physical and Chemical Properties for Agro-K Yeast Hydrolysate Liquid MUP		
Guideline Reference No./Property	**Description of Result**	**Methods**
830.6303 Physical State	Dry powder	Visual observation at room temperature
830.6317 Storage Stability	Storage stability study should be conducted in conjunction with the corrosion characteristics study, and the resulting report will be submitted to EPA upon completion.	
830.6320 Corrosion Characteristics	Corrosion characteristics should be conducted with the storage stability study, and a combined storage and corrosion characteristics report will be submitted to EPA.	
830.7000 pH	3-3.5 at 23°C	
830.7300 relative density (specific gravity)	1.07 (8.95 lbs gallon)	

[a]Data from MRIDs 49097701

8) Toxicology

Acute studies are required for this MUP. The applicant chose to use the Cite All to cover all toxicology requirements; however, the registered products in the Agency data base reflect products that have different applications, inerts, and exposure potential. The 870.1100 Acute Oral Toxicity is fulfilled with an $LD_{50} > 5{,}000$ mg/kg (Toxicology Category IV) (USEPA 2004). The applicant must submit the following studies or an appropriate waiver request with relevant justification: 870.1200 Acute dermal; 870.1300 Acute Inhalation; 870.2400 Primary Eye Irritation; 870.2500 Primary Dermal Irritation; 870.2600 Dermal Sensitization.

Deficiencies: Required acute test

9) Ecological Non-Target Testing

Since this is a non registered source the applicant must submit acute ecological non-target studies or appropriate rationale to support request for waivers. The required studies include the following: 850.2100 Acute Avian Oral; 850.2200 Acute Avian Dietary; 850.1075 Acute Freshwater Fish; 850.1010 Acute Aquatic Invertebrate.

Deficiencies: Required acute toxicity studies

References

Smith, C. (2008) Bull Run Attractant: Effects on Non-Target Organisms. Unpublished study prepared by Bull Run Scientific, VBT. 7 p. (MRID 47396909)

Smith, C. (2008) Bull Run Fly Attractant: Tier I Mammalian Toxicology. Unpublished study prepared by Bull Run Scientific, VBT. 8 p. (MRID 47396911)

Smith, C. (2008) Yeast: Effects on Non-Target Organisms. Unpublished study prepared by Bull Run Scientific, VBT. 6 p. (MRID 47396937)

Smith, C. (2008) Yeast: Tier 1 Mammalian Toxicology. Unpublished study prepared by Bull Run Scientific, VBT. 8 p. (MRID 47396938)

USEPA Biopesticides Registration Action Document Yeast Extract Hydrolysate from *Saccharomyces cerevisiae* February 2, 2004